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JULY 23, 2021 BY RONNIE

FDA Stopping Emergency Authorized PCR Tests? Not Approved In Canada Either

The screenshot shows the CDC Division of Laboratory Systems (DLS) website. At the top, the CDC logo and text "Centers for Disease Control and Prevention" are visible, along with the tagline "CDC 24/7: Saving Lives. Protecting People™". A search bar and "Advanced Search" link are on the right. Below the header, the "Division of Laboratory Systems (DLS)" title is displayed. The main content area features a "Lab Alert" titled "07/21/2021: Lab Alert: Changes to CDC RT-PCR for SARS-CoV-2 Testing". The alert includes a graphic with the CDC logo and the "LOCS" (Laboratory Outreach Communication System) logo. Below the graphic, the "Audience" is listed as "Individuals Performing COVID-19 Testing" and the "Level" is "Laboratory Alert". A left sidebar contains navigation links: "DLS Home", "About Us", "LIVD Mapping Tool for SARS-CoV-2 Tests", "Strengthening Clinical Laboratories", and "CDC's Laboratory Outreach Communication System (LOCS)".

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People™

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LIVD Mapping Tool for SARS-CoV-2 Tests

Strengthening Clinical Laboratories

CDC's Laboratory Outreach Communication System (LOCS)

07/21/2021: Lab Alert: Changes to CDC RT-PCR for SARS-CoV-2 Testing

Audience: Individuals Performing COVID-19 Testing

Level: Laboratory Alert

LOCS Laboratory Outreach Communication System

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Testing devices for COVID-19: Nucleic acid testing devices

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The FDA has allowed so called RT-PCR testing under the pretense that it's effective for virus detection. It has been given emergency use authorization, which is set to run out in December 2021. Okay, what will take its place, or will this whole hoax come to an end?

"After December 31, 2021, ***CDC will withdraw the request to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel***, the assay first introduced in February 2020 for detection of SARS-CoV-2 only. CDC is providing this advance notice for clinical laboratories to have adequate time to select and implement one of the many FDA-authorized alternatives."

Public health officials in Canada always talk about how they are "following the science". Turns out, at least part of it has been farmed out to the United States. And what is adopted here is sketchy, at best. If Canada is relying on this "testing" method, and the U.S. stops, what happens here?

Read between the lines on Health Canada's own website.

Health Canada refers to guidance published by the US Food and Drug Administration (FDA) on nucleic acid-based tests:

-for testing devices intended for laboratory or point-of-care use, ***please refer to FDA's guidance on molecular -tests***

-for testing devices intended for self-testing, ***please review the FDA guidance*** for molecular and antigen tests for non-laboratory use

-Manufacturers ***following the FDA guidance*** for molecular and antigen tests for non-laboratory use should note that Health Canada expects them to follow the guidance for non-prescription testing. This is because the distinction made by the FDA between prescription and non-prescription testing does not exist in Canada.

The FDA, ***Food & Drug Administration, guidances are in a template format and outline requirements that these products must meet.***

Health Canada says in its own guidelines that it uses the USFDA as a reference point in how nucleic-acid based tests are conducted. That's quite interesting considering that the FDA's own tests are not approved, but instead have emergency use authorization. And that is set to lapse at the end of 2021. And it's about to get more interesting from that.

Now, FDA approval is different than FDA emergency use authorization. This parallels Health Canada, in which approval is different than interim authorization. The FDA lists a few circumstances where EUA will be given. The following is from their site:

1. A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a CBRN agent(s);
2. A determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a CBRN agent(s);
3. ***A determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency***, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent(s);
4. The identification of a material threat, by the Secretary of Homeland Security pursuant to

section 319F-2 of the Public Health Service (PHS) Act, that is sufficient to affect national security or the health and security of United States citizens living abroad.

Presumably, the emergency use authorization is granted under #3. However, the document makes it clear that this is not the same thing as being approved. Furthermore, when the emergency is over, sales and distributions of such products must end.



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FDA guidance: Molecular diagnostic template for commercial manufacturers

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Health Canada links that FDA document on their own site. Presumably, this is used as a starting point for how the Canadian Government handles such things.

Under Section B on that same page, Health Canada lists the “specific nucleic acid sequences from the genome of the SARS-CoV-2 (please specify the targeted gene(s) of the pathogen).” In other words, these tests are not supposed to test for an isolated virus, but to test for a gene, or a portion of a virus — assuming it exists.

The World Health Organization also doesn’t think isolating a virus is necessary. See page 3 of its March 2020 guidance, page 8 of its September 2020 guidance.

Health Canada, again, same page, asks companies applying for an authorization to disclose the known limitations of their testing equipment. On F, Proposed Intended Use, it provides the following:

- **Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.** Negative results must be combined with clinical observations, patient history and epidemiological information.
- **Negative results from pooled samples should be treated as presumptive.** If inconsistent with clinical signs and symptoms or necessary for patient management, pooled samples should be tested individually. Negative results do not preclude SARS-CoV-2 infection and must not be used as the sole basis for patient management decisions. **Negative results must be considered in the context of a patient's recent exposures, history,** presence of clinical signs and symptoms consistent with COVID-19.
- Use of the [test name] in a general, asymptomatic screening population is intended to be used as part of an infection control plan, that may include additional preventative measures, such as a predefined serial testing plan or directed testing of high-risk individuals. **Negative results should be considered presumptive and do not preclude current or future infection obtained through community transmission or other exposures.** Negative results must be considered in the context of an individual's recent exposures, history, presence of clinical signs and symptoms consistent with COVID-19.

These are what Health Canada lists as examples (emphasis mine). In other words, the tests, if negative, don't really mean negative. It must be taken in context of other factors. This is a long way away from being the "gold standard" that we are always told it is.

Such guidelines seem ripe for abuse, as a test result could mean whatever the person wants it to be. The above disclaimer means that it's very subjective, and unreliable as a standardized medical or scientific device.

The BC Centre for Disease Control admitted in April 2020 that the tests are useless. If they can't detect infection, and the actual error rate is unknown, then they are of no help, other than to artificially drive up false positives. Also, let's not forget this now scrubbed article of Bonnie Henry admitting false positives could overburden the hospitals. Does this virus even exist?

Other provinces, like Ontario and Manitoba, claim that PCR tests are the "gold standard". At testing what exactly?

It's not just nucleic acid tests (or PCR tests) that are held to virtually non-existent standards. Other tests follow the same pattern.



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FDA guidance: Antigen template for test developers

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Results are for the identification of SARS-CoV-2 [protein name]antigen. Antigen is generally detectable in [specimen type]during the acute phase of infection. ***Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.*** Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

The [test name] is intended for use by [include intended user, for example, trained clinical laboratory personnel specifically instructed and trained in vitro diagnostic procedures]. The [test name] ***is only for use under the Food and Drug Administration's Emergency Use Authorization.***

Under Section F: Proposed intended use, there are some rather lengthy disclaimers to be added in. In short, these tests are to be used as an emergency authorized test by the FDA, not approved.

Beyond that, the test results are meaningless. A positive result could be a false positive, and a negative result could be a false positive. It's only to be used in conjunction with a patient's history. Again, this is completely subjective.

Interim Orders, like this one signed on March 30, 2020, allow medical devices and medications to be distributed in Canada, even if they don't meet all the regulatory conditions. In short, as long as there is an "emergency", there will always be a way to get them into the market.

That Order since lapsed, and Patty Hajdu signed another one on March 1, 2021. Theoretically, as long as this keeps getting extended, then Health Canada will never need to make a determination as to whether these products are safe.



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Requirements for serological antibody tests submitted under the COVID-19 Interim Order: guidance

i This guidance remains in effect, however, the [Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19](#) has been replaced by [Interim Order No. 2 respecting the importation and sale of medical devices for use in relation to COVID-19](#). Stakeholders should read references to the numbered provisions of Interim Order No. 1 that appear in this guidance as references to the equivalent provisions in Interim Order No. 2.

Note: As research evolves and we learn more about the virus, the disease and the immune response, the requirements in this Guidance may be updated based on the latest scientific evidence

Limitations related to the intended use of serological tests

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Based on the information available at the present time, **Health Canada will not authorize serological tests intended to be used for diagnosis or for self-testing**. As research evolves and we learn more about the virus, the disease and the immune response, the

requirements in this Guidance may be updated accordingly based on available scientific evidence.

The following statements should be ***included as limitations of serological tests***:

- This assay is not intended to be used for screening patients or as an aid for diagnosis of patients with suspected COVID-19 infection.
- This assay is not intended for home testing (or self-testing).
- Negative results do not preclude SARS-CoV-2 infection*** and should not be used as the sole basis for patient management decisions.
- Negative results must be combined with clinical observations, patient history, and epidemiological information.***
- False negative results can occur in elderly and immunocompromised patients.
- False positive results for IgM and IgG antibodies*** may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The above listings are limitations of serology testing. All of these tests come with a common disclaimer: we don't know that they actually work.

If people haven't figured out by now that this is all a scam, then they probably never will. This is obvious to anyone paying attention.

(1) https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html

(2) <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/testing/nucleic-acid-devices.html>

(3) <https://archive.is/HaFdq>

(4) http://www.bccdc.ca/Health-Professionals-Site/Documents/COVID19_InterpretingTesting_Results_NAT_PCR.pdf

(5) https://canucklaw.ca/wp-content/uploads/2021/01/BC-COVID19_InterpretingTesting_Results_NAT_PCR.pdf

(6) <https://canucklaw.ca/wp-content/uploads/2021/01/WHO-COVID-19-laboratory-Testing-March-17-2020.pdf>

(7) <https://canucklaw.ca/wp-content/uploads/2021/01/WHO-2019-nCoV-laboratory-September-11-2020-Guidelines.pdf>

(8) <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/testing/antigen-devices/fda-guidance-molecular-diagnostic-template->

[commercial-manufacturers.html](#)

(9) <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/covid19-requirements-serological-antibody-tests.html>

(10) <https://archive.is/ISGAH>

(11) <https://archive.is/hyKJj>

(12) https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html

(13) <https://archive.is/oc5OY>

(14) <https://www.fda.gov/media/97321/download>

(15) [FDA Emergency Use Guidelines](#)

(16) <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/testing/antigen-devices/fda-guidance-antigen-template-test-developers.html>

(17) <https://archive.is/wASc9>

(18) <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods.html>

(19) <https://archive.is/sPj1p>

(20) <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drug-medical-device-food-shortages/interim-order-2021.html>

(21) <https://archive.is/n3dPV>

(22) <https://archive.is/U2k6g>

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2 Replies to “FDA Stopping Emergency Authorized PCR Tests? Not Approved In Canada Either”



Andrew

JULY 24, 2021 AT 8:54 AM

It's interesting that they're planning to change the testing method right after Gates and Soros just bought a Covid-19 testing company.



xpapar

JULY 26, 2021 AT 4:52 AM

Yes called and you can not make this up, it is called Mologic.